Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QPS-0537-20**

Addendum n° *addendum no.* **01-20**

Data prima emissione *First issue date* **29.07.2020**
Data di emissione corrente *Current issue date* **06.08.2020**
Data di scadenza *Expiry date* **26.05.2024**

GARANZIA DELLA QUALITA' DELLA PRODUZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni per i soli aspetti della fabbricazione che riguardano il raggiungimento e il mantenimento dello stato sterile
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

PRODUCTION QUALITY ASSURANCE

according to Annex V of EC Directive 93/42/EEC and subsequent modifications and integrations for only the aspects of manufacture concerned with securing and maintaining sterile conditions
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema di garanzia della qualità per i soli aspetti della fabbricazione che riguardano il raggiungimento e il mantenimento dello stato sterile attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the quality assurance system for only the aspects of manufacture concerned with securing and maintaining sterile conditions enforced by

STS MEDICAL GROUP AD

***Sede Legale/** Registered Office:*
Industrial Area "Sokolovetz"- 2800 Sandanski - BULGARIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:

Sede Produttiva/** Production Site: **Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria
Sede Operativa/** Operative Office: **Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria
Sede Amministrativa/**Administrative Office: **Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria

per il dispositivo/i *for the device(s)*

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* **L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPS-0537-20**

Addendum n° / *addendum no.* //-//

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Compresse Oculari sterili (famiglia M05)	*11XXX NU-XXXXXXXXXX, 194XXX*
Compresse per farmacia sterili in garza o tnt (famiglia M21)	*3XXXX, SALXXXX NU-XXXXXXXXXX, 194XXX 274XXX, 15400Y⁴, 15400SY⁴, 15400Y⁴-01, 15400SY⁴-01,*
Calzari in maglia tubolare sterili (famiglia M13)	*54XXX*
Pinze, Rasoi, forbici in busta sterile (famiglia M30)	*7XXXX*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° *The Certificate no.* **QPS-0537-20**

Addendum n° *addendum no.* //-//

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Tamponi di cotone sterile, Tamponi di cotone/rete sterile	*SEXXXX, 11XXX*
Kit vari sterili (famiglia M30)	*2XXXX – 4XXXX – 5XXXX - 6XXXX – 8XXXX SEXXXX, 03XXXX, XXXXCE, TPXXXXXXCE WHHDPXXXCE, HCMXXX, 2XXXX-01, 2XXXX-02, 2XXXXY Y [4], 2XXXXY [4] 2XXXXY [4] 2Y [4], 2XXXXY [4]-01, 2XXXXY [4]-03 2XXXXY [4]-04, 9XXXX, 9XXXX-01, 9XXXX-02 9XXXXBG, DMXXXX, DEVICECRT1, DEVICECRT2, ZAS3, 9642800*
Reimplantation bags	*CPCXXXX CPCXXXX-01*
Medicazioni adesivi TNT LUXOR	*26XXX*

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

[1]X indicano le variazioni di misura, tipo di garza e numero degli strati

[2]MI: Metal Instrument; XXX: codice progressivo; YY: indica le varie lunghezze degli strumenti appartenenti alla stessa famiglia, ; X indica lo stato "sterile" del dispositivo.

[3]CP: indica la famiglia del dispositivo medico; XXXXX: codice progressivo.

[4] XXXX: codice progressivo; Y: lettera progressiva; Y Y: doppia lettera progressiva

Valutazione della Conformità: vedi MOD-341-01-01 n. 351/20
Conformity assessment: see MOD-341-01-01 n. 351/20

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Ragione sociale
STS Medical Group AD
Industrial area Sokolovets
2800 Sandanski Blagoevgrad Bulgaria

29-Jul-24

Notified Body Confirmation Letter
Reference: contract n. 000133089

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

STS Medical Group AD
Industrial area Sokolovets
2800 Sandanski Blagoevgrad Bulgaria
SRN manufacturer: BG-MF-000041809
SRN procedure pack producer: BG-PR-000041814

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the ICIM has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

ICIM SPA
Piazza Don Enrico Mapelli, 75
20099 Sesto San Giovanni MI
Identification on NANDO CE0425

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Table 1: Devices covered by this letter and for which ICIM SPA is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Table 2: Devices covered by this letter and for which ICIM SPA is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SECUSORB: compresses, balls, pads, laparotomy sponges, adhesive dressings	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUTOOL: single-use surgical instruments	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUTRAY: sterile procedure packs	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUSORB: compresses, balls, pads, laparotomy sponges, adhesive dressings	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità
SECUTOOL: single-use surgical instruments	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità
SECUTRAY: sterile procedure packs	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/07/19	00	Initial issue

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

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Mr. Edoardo Dossena
Sales Responsable Manager

Miss. Flavia Lepore
Sales Director

Straytegic Industry
ICIM S.p.A.

ICIM S.p. A.

ICIM SpA Società soggetta all'attività di direzione e coordinamento di ICIM GROUP Srl
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - Tel. +39 02 725341 Fax +39 02 72002098 - www.icim.it - info@icim.it
Capitale sociale € 260.000,00 int. versato ed esistente - C.F./P.IVA e Iscriz. Reg. Imprese di Milano n. 12908230159 – R.E.A. n. 1596292